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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,847

08/04/2003

Neil J. Bulleid

39-286

5853

23117 7590 11/16/2009
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EXAMINER

HILL, KEVIN KAI

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

11/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/632,847	Applicant(s) BULLEID, NEIL J.	
	Examiner KEVIN K. HILL	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-47 is/are pending in the application.
- 4a) Of the above claim(s) 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Detailed Action
Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 15, 2009 has been entered.

Election/Restrictions

Applicant has elected with traverse the invention of Group I, Claims 29-44, drawn to a method of producing pro-collagen comprising expressing a nucleic acid in an isolated cell.

Claims 45-47 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on October 26, 2006. In the Office Action of December 11, 2006, the restriction/election requirement was made FINAL. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 28-44 are under consideration.

Priority

This application is a continuation of application 09/380,377, filed September 16, 1999, which is a 371 application of PCT/GB98/00468, filed March 2, 1998. Applicant's claim for the benefit of a prior-filed application 09/380,377 under 35 U.S.C. 119(e) and PCT/GB98/O0468 under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Acknowledgment is also made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of UK 9704305.3, filed March 1, 1997, has been filed in parent application 09/380,377, filed September 16, 1999.

Accordingly, the effective priority date of the instant application is granted as March 1, 1997.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the May 15, 2009 response will be addressed to the extent that they apply to current rejection(s).

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

1. **Claims 28-37 and 39-43 stand rejected on the ground of nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-3, 5-6, 12-13 and 17-19 of Bulleid et al, U.S. Patent No. 6,171,827 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method and materials to perform said method claimed in the instant application are encompassed by the patented method(s) and patented materials to perform said patented method(s).

Response to Arguments

Applicant argues that the method requires that a first procollagen be produced in a cell that expresses and assembles a second procollagen; however, no such cell is taught by the claims of US 6,171,827. The Examiner has provided no basis in fact and/or technical reasoning as to why the expression host cell that may be eukaryotic, including yeasts, insects and mammalian cell lines ('872; col. 5, lines 64-66) would inherently express an endogenous pro-collagen molecule.

Applicant's argument(s) has been fully considered, but is not persuasive. Claim 19 of '827 claims a method of producing a collagen in a host cell, said collagen molecule having the structural and functional properties (Claim 1 of '827). Because Bulleid et al use the generic term "expression host cell", the Examiner had looked to the specification to better understand the nature of the invention. Bulleid et al disclose that the expression host cell may be eukaryotic, including yeasts, insects and mammalian cell lines (col. 5, lines 64-66). To show the facts asserted to be common knowledge in the art capable of instant and unquestionable demonstration as being well-known, the Office now provides Oikarinen et al (Biochem. J. 245:235-241, 1987), who demonstrates that it was a well known knowledge that eukaryotic cells, e.g. mammalian cell lines ('872; col. 5, lines 64-66), i.e. HT1080 ('872; col. 9, line 2), express and assemble a second procollagen. Accordingly, the Examiner's basis for inherency is supported by facts to be well-known or to be common knowledge in the art and are capable of instant and unquestionable demonstration as being well-known. Thus, those of ordinary skill in the art would immediately

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recognize the instantly claimed method is necessarily performed in the claimed method of producing collagen in said host cell of '872.

Applicant argues that the instant claims require the expression in the cell of nucleic acid sequence(s) that encode(s) a pro- α chain for assembly into the first procollagen, which nucleic acid sequence(s) do/does not encode pro- α chain(s) that co-assemble with the pro- α chains that assemble to form the second procollagen. Nothing in the cited patent claims are even suggestive of this further requirement.

Applicant's argument(s) has been fully considered, but is not persuasive. The pro- α chains recited in the U.S. Patent No. 6,171,827 B1 are the same as the pro- α chains recited in the instant application, and thus the functional limitation that the pro- α chain does not co-assemble with pro- α chains that assemble to form said second collagen is an inherent feature of the claimed pro- α chains. Although the functional properties of the pro- α chains are recited in the instant application, the patented pro- α chains used in the patented method are structurally the same, or in the case of SEQ ID NO:6 (instant)/SEQ ID NO:11(patent) substantially similar to, the instantly recited pro- α chains used in the instantly recited method. "Products of identical chemical composition can not have mutual exclusive properties." A compound and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705,709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP §2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant has provided no evidence that the patented pro- α chains used in the patented method would not possess the instantly recited functional properties.

2. **Claims 28-33 and 35-43 stand rejected under 35 U.S.C. 102(e)** as being anticipated by Bulleid et al (U.S. Patent No. 6,171,827 B1).

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Response to Arguments

Applicant argues that the method requires that a first procollagen be produced in a cell that expresses and assembles a second procollagen; however, no such cell is taught by the claims of US 6,171,827. The Examiner has provided no basis in fact and/or technical reasoning as to why the expression host cell that may be eukaryotic, including yeasts, insects and mammalian cell lines ('872; col. 5, lines 64-66) would inherently express an endogenous pro-collagen molecule.

Applicant's argument(s) has been fully considered, but is not persuasive. Claim 19 of '827 claims a method of producing a collagen in a host cell, said collagen molecule having the structural and functional properties (Claim 1 of '827). Bulleid et al disclose that the expression host cell may be eukaryotic, including yeasts, insects and mammalian cell lines (col. 5, lines 64-66). To show the facts asserted to be common knowledge in the art capable of instant and unquestionable demonstration as being well-known, the Office now provides Oikarinen et al (1987), who demonstrates that it was a well known knowledge that eukaryotic cells, e.g. mammalian cell lines, i.e. HT1080 ('872; col. 9, line 2) express and assemble a second procollagen. Accordingly, the Examiner's basis for inherency is supported by facts to be well-known or to be common knowledge in the art and are capable of instant and unquestionable demonstration as being well-known. Thus, those of ordinary skill in the art would immediately recognize the instantly claimed method is necessarily performed in the claimed method of producing collagen in said host cell of '872.

Applicant argues that the instant claims require the expression in the cell of nucleic acid sequence(s) that encode(s) a pro- α chain for assembly into the first procollagen, which nucleic acid sequence(s) do/does not encode pro- α chain(s) that co-assemble with the pro- α chains that assemble to form the second procollagen. Nothing in the cited patent claims are even suggestive of this further requirement.

Applicant's argument(s) has been fully considered, but is not persuasive. The pro- α chains recited in the U.S. Patent No. 6,171,827 B1 are the same as the pro- α chains recited in the instant application, and thus the functional limitation that the pro- α chain does not co-assemble with pro- α chains that assemble to form said second collagen is an inherent feature of the

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claimed pro- α chains. Although the functional properties of the pro- α chains are recited in the instant application, the patented pro- α chains used in the patented method are structurally the same, or in the case of SEQ ID NO:6 (instant)/SEQ ID NO:11(patent) substantially similar to, the instantly recited pro- α chains used in the instantly recited method. "Products of identical chemical composition can not have mutual exclusive properties." A compound and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705,709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP §2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Applicant has provided no evidence that the patented pro- α chains used in the patented method would not possess the instantly recited functional properties. Applicant's terse statements do not shed light on how the instant application is clearly distinguished from Bulleid et al, nor how Bulleid et al, as a whole, specifically fail to teach the instantly claimed invention.

3. **Claims 28-33 and 35-43 stand rejected under 35 U.S.C. 102(f)** because the Applicant did not invent the claimed subject matter. The prior art reference (U.S. Patent No. 6,171,827 B1) establishes that two individuals, Neil Bulleid and Karl Kadler, are the inventors of the claimed subject matter.

Response to Arguments

Applicant argues that the rejection is based upon the Examiner's misunderstanding of the reference.

Applicant's argument(s) has been fully considered, but is not persuasive. As discussed in the prior Office Action, it is incumbent upon the inventors named in the application, in reply to an inquiry regarding the appropriate inventorship under subsection (f), or to rebut a rejection under 35 U.S.C. 102(a) or (e), to provide a satisfactory showing by way of affidavit under 37 CFR 1.132 that the inventorship of the application is correct in that the reference discloses subject matter invented by the Applicant rather than derived from the author or patentee notwithstanding the authorship of the article or the inventorship of the patent. *In re Katz*, 687

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F.2d 450, 455, 215 USPQ 14, 18 (CCPA 1982) (inquiry is appropriate to clarify any ambiguity created by an article regarding inventorship, and it is then incumbent upon the Applicant to provide "a satisfactory showing that would lead to a reasonable conclusion that [Applicant] is the...inventor" of the subject matter disclosed in the article and claimed in the application). See MPEP §2137.

Claim Rejections - 35 USC § 103

4. **Claims 28-44 stand rejected under 35 U.S.C. 103(a)** as being obvious over Bulleid et al (U.S. Patent No. 6,171,827 B1) in view of Barr et al (U.S. Patent No. 5,460,950).

Applicant's Arguments

Applicant argues that nothing in Barr et al cures the deficiency of Bulleid et al.

Applicant's argument(s) has been fully considered, but is not persuasive. As discussed in the prior Office Action, the Examiner's response to what is taught by Bulleid et al is discussed above, and is incorporated herein. Barr et al is applied for teaching that the art recognized BHK, 3T3, CHO and COS cells, recited in Claim 44, were generally useful for the expression of exogenous proteins (Barr et al, column 14, lines 7-35).

Conclusion

5. No claims are allowed.

This is a continuation of Applicant's earlier Application No. 10/632,847. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/

Examiner, Art Unit 1633